SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6361–6380

Adulteration, Section 501(a)(1), the article consisted in part of a filthy substance; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling; Section 502(l), the article was composed wholly or in part of penicillin, or chloramphenicol, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

DEVICE FOR HUMAN USE

6361. Thiede's head harness. (F.D.C. No. 44757. S. No. 18–041 R.)

QUANTITY: 2 devices at Billings, Mont.

SHIPPED: About March 1959, from Idaho Falls, Idaho, by Thiede Enterprise, Inc.

LABEL IN PART: "Thiede's Stretch to Health Head Harness Company, Idaho Falls, Idaho."

ACCOMPANYING LABELING: Pamphlet entitled "A Simple Improved Method for Vertebral Traction."

RESULTS OF INVESTIGATION: The article consisted of a head harness and accessories intended for supporting the head while the rest of the body would dangle, thus pulling on the neck muscles.

LIBELED: 7–27–60, Dist. Mont.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used as directed in its labeling.

DISPOSITION: 8–23–60. Default—destruction.

DRUG FOR VETERINARY USE

6362. Black Widow Smear (veterinary). (F.D.C. No. 44705. S. No. 19–184 R.)

QUANTITY: 6 16-oz. jars, 10 32-oz. jars, and 4 1-gal. jars at Artesia, N. Mex.

SHIPPED: 10–3–59, from Booker, Tex., by Brewer & Johnson.

LABEL IN PART: "Black Widow Smear A Worm Killer, Healer and Repellant. * * * Active Ingredients: Castor Oil 17.25%; Benzol 30.48%: Coal Tar Natural Oils 19.00%; Soap 12.90%; Coal Tar Phenols 6.44% * * * Manufactured & Distributed by Brewer & Johnson * * * Booker, Texas."

LIBELED: 7–5–60, Dist. N. Mex.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for pink eyes in livestock; and 502(j)—the article was dangerous to health when used in the dosage, or with the frequency or duration recommended or suggested in its labeling, namely, "Directions—For screw worms apply in and around wound. For pink eyes apply around the eyes with a brush or wooden paddle. Dehorning: Apply IN AND AROUND but DON'T FILL HORN. Castration, wire cuts, apply in and around area. Fleece worms apply in and around infected parts. Ear Ticks, use brush and apply inside of ear."

DISPOSITION: 8–8–60. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6363. Delfetamine tablets. (F.D.C. No. 44683. S. Nos. 40–625/6 R.)

QUANTITY: 3 drums, containing respectively 40,900 tablets, 36,100 tablets, and 22,000 tablets, at St. Louis, Mo.

SHIPPED: 5–2–60 and 5–12–60, from Baltimore, Md. These were return shipments.

LABEL IN PART: "Delfetamine . . . 30 mg. Stedytabs Each tablet contains: *Delfetamine . . . 30 mg. Caution * * * Average Dose * * * *Registered Trademark of dl-N-methyl-beta phenylisopropylamine Hydrochloride."

LIBELED: 6–24–60, E. Dist. Mo.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 9–8–60. Default—destruction.

6364. Allergy capsules and Trim-All capsules. (F.D.C. No. 44570. S. Nos. 25–909/10 R.)

QUANTITY: 1 drum containing about 10,000 *allergy capsules* and 1 ctn. containing about 15,000 *Trim-All capsules* at N. Hollywood, Calif., in possession of Windsor Corp.

SHIPPED: 10–15–59, from Englewood, N.J., by Zenith Laboratories, Inc.

LABEL IN PART: (Drum) "Zenith Laboratories, Inc., Englewood, New Jersey 1 Carton Containing 10M T.D. Capsules Each capsule contains: Pyrilamine Maleate 30 mg. Phenylephrine HCl 15 mg. Chlorprophenpyridamine 5 mg. * * * Lot No. 923765 TO: Windsor Corporation * * * North Hollywood, Calif."; (box) "Allergy Capsules * * * Anti-Allergy (Timed Disintegrating Capsules) For use as a Decongestant in Vasomotor Rhinitis, and in the symptomatic treatment of Urticaria, Hay fever and Asthma * * * Each capsule contains * * * 45129 Windsor Corporation"; (ctn.) "Zenith Laboratories, Inc., Englewood, New Jersey 1 Carton Containing 25M T.D. Capsules Each Capsule contains: Phenylpropanolamine 60 mg. Sodium Caseinate 2 gr. Dextrose 2 gr. Ascorbic Acid 50 mg. * * * Lot No. 928095 * * * TO: Windsor